

**REMARKS****Restriction/Election**

In the March 20, 2009 Office Action, the Examiner imposed a species election under PCT Rule 13.1. Specifically, the Examiner required that an election be made between:

- (a) species 1, detecting an autoimmune disease;
- (b) species 2, detecting a vascular disease; or
- (c) species 3, obstetric complications.

Applicants elect, with traverse, species 3 relating to obstetric complications, in particular fetal death (see, e.g., claim 6).

In addition, the Examiner required that an election be made between:

- (i) species 1, a polypeptide comprising the sequence of amino acids of full length EPCR (claim 11);
- (ii) species 2, a polypeptide comprising the sequence of amino acids of a fragment of EPCR containing at least one epitope capable of being recognized by an anti-EPCR autoantibody (claim 11);
- (iii) species 3, a fusion protein (claims 12-17 and 35-36);
- (iv) species 4, a fusion protein comprising the sequence of amino acids of the soluble part of human EPCR, the sequence of amino acids corresponding to c-myc epitope and a tail of histidines (claims 18 and 37); or
- (v) species 5, a fusion protein comprising SEQ ID NO: 3 (claims 19 and 38).

Applicants elect, with traverse, species 2 (claim 11) relating to a polypeptide comprising the sequence of amino acids of a fragment of EPCR containing at least one epitope capable of being recognized by an anti-EPCR antibody.

The traversals are based on the fact that the European Patent Office (EPO), acting as the International Search Authority of the international patent application PCT/ES2005/000046, from which the pending U.S. application derives, has already reviewed the unity of invention issue. In fact, the International Search Report (ISA) concluded that all claims met the requirement of unity of invention since no

objections on said requirement was issued. Therefore, the ISA has found that the present invention relates to “one invention only or to a group of inventions so linked as to form a single general inventive concept” (PCT Rule 13.1).

The EPO has applied the PCT rules to the present invention without finding a lack of unity of invention. Therefore, the USPTO cannot now apply a different standard to the present invention than the EPO.

In addition, applicants do not agree with the opinion of the Examiner regarding the need for restricting the claims. As required under PCT rule 13.1, the claims are all linked so as to form a single general inventive concept, namely that detection of anti-EPCR autoantibodies using a EPCR derived peptide allows the determination of the risk and predisposition to develop a pathology related to the presence of anti-EPCR autoantibodies. No document has been cited by the Examiner showing that the above concept is known from the prior art. Thus, applicants submit that the claimed subject matter meets the unity of invention requirement.

In the event that the Examiner maintains the election requirements, the election herein includes claims 6 and 11 in addition to all of the generic claims. Further, applicants acknowledge the Examiner's indication that examination will begin with the elected species and upon allowance of the elected species, the search will be expanded by the Examiner to consider additional species and subgenres within the generic formula.

#### **Petition for Extension of Time/Fees Payable**

Applicants hereby petition for a one (1) month extension of time, extending the deadline for responding to the March 20, 2009 Office Action from April 20, 2009 to May 20, 2009. As such, the fee of \$130.00 specified in 37 CFR §1.17(a)(1) for such one (1) month extension is due.

The total fee of \$130.00 is being paid using Electronic Funds Transmission. Authorization is also hereby given to charge any deficiency in applicable fees, or credit any overcharges, for this response to Deposit Account No. 13-4365 of Moore & Van Allen PLLC.

#### **Conclusion**

If any additional issues remain, the Examiner is requested to contact the undersigned attorney at (919)

286-8000 to discuss same.

Respectfully submitted,

**MOORE & VAN ALLEN PLLC**

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By:



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